

IN THE CLAIMS:

Claims 1-69 previously cancelled by preliminary amendment.

Cancel claims 70-89 without prejudice or disclaimer. Present status of the claims is as follows:

Claim 1. (cancelled)

A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body;
- (b) implanting at least one electrode to be in communication with a vagus nerve of said body;
- (c) coupling said one or more electrodes to said signal generator;
- (d) operating the signal generator to provide stimulation pulses to the vagus nerve via the electrodes;
- (e) generating a sensor signal indicative of a characteristic of a heart; and
- (f) regulating said stimulation pulses in response to said sensor signal, whereby epilepsy is treated.

Claim 2. (cancelled)

A method as claimed in claim 1, wherein said step of regulating comprises the step of executing a control algorithm.

Claim 3. (cancelled)

A method as claimed in claim 1, wherein said step of generating a sensor signal provides instantaneous heart rate information.

Claim 4. (cancelled)

A method as claimed in claim 1, wherein said step of generating a sensor signal provides heart rate variability information.

Claim 5. (cancelled)

A method as claimed in claim 1, wherein said step of implanting the electrode includes the step of positioning the electrode to selectively stimulate slow conducting vagus nerve fibers.

Claim 6. (cancelled)

A method as claimed in claim 1, wherein the step of regulating includes the step of adjusting at least one characteristic of the stimulation pulses, wherein the characteristic is selected from the group consisting of pulse shape, inter-stimulus interval, pulse frequency, pulse width, pulse amplitude and pulse phase.

Claim 7. (cancelled)

A method as claimed in claim 1, wherein the step of operating the signal generator is performed in response to a sensing of a possible onset of a seizure.

Claim 8. (cancelled)

A method as claimed in claim 1, wherein the step of operating the signal generator is performed in response to a user operating a switch to activate the signal generator.

Claim 9. (cancelled)

A system for controlling or preventing epileptic seizures comprising in combination:

- (a) an implantable signal generator providing stimulation energy;
- (b) at least one electrode having a proximal end coupled to said signal generator and a distal end adapted to provide stimulation to a vagus nerve of a patient;
- (c) a sensor for generating a sensor signal indicative of a characteristic of a heart; and
- (d) control means responsive to said sensor signal for regulating said stimulation.

Claim 10. (cancelled)

The system of claim 9 further comprising:

- (e) a switch coupled to the signal generator and operable by the patient, whereby the patient may manually turn on or off the vagus nerve stimulation.

Claim 11. (cancelled)

The system of claim 9 further comprising:

- (e) a second sensor generating a second sensor signal indicative of a possible onset of a seizure, and wherein the signal generator is responsive to the second sensor signal.

Claim 12. (cancelled)

The system of claim 11, wherein the second sensor is implantable to be in communication with a brain of the patient.

Claim 13. (cancelled)

The system of claim 9, wherein the signal generated by the sensor is selected from the group consisting of an instantaneous heart rate (IHR) signal and a heart rate variability signal.

Claim 14. (cancelled)

The system of claim 9, wherein the signal generated by the sensor is of heart pulse.

Claim 15. (cancelled)

The system of claim 9, wherein the signal generated by the sensor is a rate of change of a heart pulse.

Claim 16. (cancelled)

The system of claim 9, wherein the signal generated by the sensor is an electrocardiogram (EKG) of a patient.

Claim 17. (cancelled)

A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body;
- (b) implanting at least one electrode to be in communication with a vagus nerve of said body;
- (c) coupling said one or more electrodes to said signal generator;
- (d) operating the signal generator to provide stimulation pulses to the vagus nerve via the electrodes;
- (e) detecting a characteristic of a heart; and
- (f) regulating said stimulation pulses in response to said step of detecting, whereby epilepsy is treated.

Claim 18. (cancelled)

A method of minimizing effects to a heart of a patient during vagus nerve stimulation comprising the steps of:

- (a) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (b) determining whether the measured characteristic of the heart is within a normal range for the patient; and
- (c) if the heart is operating outside the normal range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

Claim 19. (cancelled)

The method of claim 18, wherein the step of adjusting stimulation includes the step of adjusting at least one characteristic of stimulation pulses provided to the vagus nerve, wherein the characteristic is selected from the group consisting of pulse shape, inter-stimulus interval, pulse frequency, pulse width, pulse amplitude, and pulse phase.

Claim 20. (cancelled)

The method of claim 18, wherein the step of adjusting includes the steps of turning off stimulation to the vagus nerve.

Claim 21. (cancelled)

The method of claim 18, further comprising the step of:

- (d) operating a pacemaker to maintain the heart within the normal range.

Claim 22. (cancelled)

The method of claim 18, further comprising the step of:

- (d) alerting the patient by way of a sensory signal.

Claim 23. (cancelled)

The method of claim 22, wherein the step of alerting includes the step of providing an audio signal to the patient.

Claim 24. (cancelled)

The method of claim 22, wherein the step of alerting includes the step of providing a vibrating signal to the patient.

Claim 25. (cancelled)

A method of minimizing effects to a heart of a patient during vagus nerve stimulation comprising the steps of:

- (a) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (b) determining whether the measured characteristic of the heart is within a normal range; and
- (c) if the heart is operating outside the normal range, alerting the patient by way of a sensory signal of effects to the heart caused by the vagus nerve stimulation.

Claim 26. (cancelled)

The method of claim 25, wherein the step of alerting includes the step of providing an audio signal to the patient.

Claim 27. (cancelled)

The method of claim 25, wherein the step of alerting includes the step of providing a vibrating signal to the patient.

Claim 28. (cancelled)

The method of claim 25, further comprising the step of:

- (d) operating a pacemaker to maintain the heart within the normal range.

Claim 29. (cancelled)

The method of claim 25, further comprising the step of:

- (d) turning off stimulation to the vagus nerve.

Claim 30. (cancelled)

A method of minimizing effects to a heart of a patient during vagus nerve stimulation comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be in communication with a vagus nerve of the body;
- (c) coupling the at least one electrode to the signal generator;
- (d) identifying at least one phase of a heart pulse during which vagus nerve stimulation has reduced effect on the heart; and
- (e) programming the signal generator to provide stimulation only during the at least one phase of the heart pulse.

Claim 31. (cancelled)

The method of claim 30, further comprising the step of:

- (f) sensing an indication of a possible onset of a seizure.

Claim 32. (cancelled)

The method of claim 31, wherein the step of sensing includes the step of sensing an electroencephalogram (EEG) of a patient.

Claim 33. (cancelled)

The method of claim 31, wherein the step of sensing includes the step of sensing a cortical signal.

Claim 34. (cancelled)

The method of claim 31, wherein the step of sensing includes the step of sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure.

Claim 35. (cancelled)

The method of claim 31, wherein the step of sensing includes the step of sensing a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability.

Claim 36. (cancelled)

The method of claim 31, further comprising the step of:

(g) if a possible seizure onset is detected, providing a warning of the possible seizure onset.

Claim 37. (cancelled)

The method of claim 36, wherein the step of warning includes the step of providing an audio signal.

Claim 38. (cancelled)

The method of claim 36, wherein the step of warning includes the step of providing a vibrating signal.

Claim 39. (cancelled)

The method of claim 30, further comprising the steps of:

(f) determining whether the measured characteristic of the heart is within a normal range; and

(g) if the heart is operating outside the normal range, alerting the patient by way of a sensory signal.

Claim 40. (cancelled)

The method of claim 30, further comprising the steps of:

- (f) determining whether the measured characteristic of the heart is within a normal range; and
- (g) if the heart is operating outside the normal range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

Claim 41. (cancelled)

The method of claim 30, further comprising the steps of:

- (f) determining whether the measured characteristic of the heart is within a normal range; and
- (g) if the heart is operating outside the normal range, turning off stimulation to the vagus nerve.

Claim 42. (cancelled)

A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be in communication with a vagus nerve of the body;
- (c) coupling that at least one electrode to the signal generator;
- (d) sensing an electroencephalogram (EEG) of a patient; and
- (e) operating the signal generator to enhance desynchronization of EEG rhythms.

Claim 43. (cancelled)

The method of claim 42, further comprising the step of:

- (f) if a possible seizure onset is detected, providing a warning of the possible seizure onset.

Claim 44. (cancelled)

The method of claim 43, wherein the step of warning includes the step of providing an audio signal.

Claim 45. (cancelled)

The method of claim 43, wherein the step of warning includes the step of providing a vibrating signal.

Claim 46. (cancelled)

The method of claim 42, further comprising the steps of:

- (f) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (g) determining whether the measured characteristic of the heart is within a normal range; and
- (h) if the heart is operating outside the normal range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

Claim 47. (cancelled)

A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be in communication with a vagus nerve of the body;
- (c) coupling that at least one electrode to the signal generator;
- (d) sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure; and
- (e) if a possible seizure onset is detected, operating the signal generator to control or prevent the epileptic seizure.

Claim 48. (cancelled)

The method of claim 47, wherein the step of sensing includes the step of sensing a heart rate.

Claim 49. (cancelled)

The method of claim 47, wherein the step of sensing includes the step of sensing a rate of change of a heart rate.

Claim 50. (cancelled)

The method of claim 47, wherein the step of sensing includes the step of sensing R-R variability.

Claim 51. (cancelled)

The method of claim 47, wherein the step of sensing includes the step of sensing a rate of change of R-R variability.

Claim 52. (cancelled)

The method of claim 47, wherein the step of sensing includes the step of sensing blood pressure.

Claim 53. (cancelled)

The method of claim 47, wherein the step of sensing includes the step of sensing a level of oxygen saturation of blood.

Claim 54. (cancelled)

A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be in communication with a vagus nerve of the body;
- (c) coupling the at least one electrode to the signal generator;
- (d) sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure; and
- (e) if a possible seizure onset is detected, warning the patient of a possible seizure onset.

Claim 55. (cancelled)

The method of claim 54, wherein the step of sensing includes the step of sensing a heart rate.

Claim 56. (cancelled)

The method of claim 54, wherein the step of sensing includes the step of sensing a rate of change of a heart rate.

Claim 57. (cancelled)

The method of claim 54, wherein the step of sensing includes the step of sensing R-R variability.

Claim 58. (cancelled)

The method of claim 54, wherein the step of sensing includes the step of sensing a rate of change of R-R variability.

Claim 59. (cancelled)

The method of claim 54, wherein the step of sensing includes the step of sensing blood pressure.

Claim 60. (cancelled)

The method of claim 54, wherein the step of sensing includes the step of sensing a level of oxygen saturation of blood.

Claim 61. (cancelled)

A system for controlling or preventing epileptic seizures comprising in combination:

- (a) an implantable signal generator providing stimulation energy;
- (b) at least one electrode having a proximal end coupled to the signal generator and a distal end adapted to provide stimulation to a vagus nerve of a patient;
- (c) a sensor for generating a sensor signal indicative of a characteristic of a heart; and
- (d) a control algorithm responsive to the sensor signal for regulating the stimulation by the signal generator to reduce any effects to the heart.

Claim 62. (cancelled)

The system of claim 61, further comprising:

- (e) a second sensor generating a second sensor signal indicative of a possible onset of a seizure, and wherein the signal generator is responsive to the second sensor signal.

Claim 63. (cancelled)

The system of claim 62, wherein the second sensor is implantable near a brain of the patient.

Claim 64. (cancelled)

The system of claim 62, wherein the second sensor is implantable within a brain of the patient.

Claim 65. (cancelled)

The system of claim 61, wherein the signal generated by the sensor is selected from the group consisting of an instantaneous heart rate (IHR) signal and a heart rate variability signal.

Claim 66. (cancelled)

The system of claim 61, wherein the signal generated by the sensor is of heart pulse.

Claim 67. (cancelled)

The system of claim 61, wherein the signal generated by the sensor is an electrocardiogram (EKG) of a patient.

Claim 68. (cancelled)

The system of claim 61, wherein the control algorithm turns off the stimulation provided by the signal generator in response to the sensor signal indicating an undesired effect on the heart from the vagus nerve.

Claim 69. (cancelled)

The system of claim 61, further comprising:

(e) a sensory stimulus responsive to the sensor signal and alerting the patient of an undesired effect on the heart from the vagus nerve.

Claim 70. (canceled)

A system for treating epileptic seizures comprising in combination:

- (a) at least one electrode having a proximal end and a distal end adapted to provide stimulation to a vagus nerve of a patient;
- (b) a sensor for generating a sensor signal indicative of a characteristic of a heart; and
- (c) an implantable signal generator coupled to the proximal end of the at least one electrode and providing stimulation energy in response to said sensor signal.

Claim 71. (canceled)

The system of claim 70 further comprising:

- (d) a switch coupled to the signal generator and operable by the patient, whereby the patient may manually turn on or off the vagus nerve stimulation.

Claim 72. (canceled)

The system of claim 70, further comprising:

- (d) a second sensor generating a second sensor signal indicative of a possible onset of a seizure, and wherein the signal generator is responsive to the second sensor signal.

Claim 73. (canceled)

The system of claim 72, wherein the second sensor is implantable to be in communication with a brain of the patient.

Claim 74. (canceled)

The system of claim 70, wherein the signal generated by the sensor is selected from the group consisting of an instantaneous heart rate (IHR) signal and a heart rate variability signal.

Claim 75. (canceled)

The system of claim 70, wherein the signal generated by the sensor is of heart pulse.

Claim 76. (canceled)

The system of claim 70, wherein the signal generated by the sensor is of a rate of change of a heart pulse.

Claim 77. (canceled)

The system of claim 70, wherein the signal generated by the sensor is an electrocardiogram (EKG) of a patient.

Claim 78. (canceled)

A method of minimizing effects to a heart of a patient comprising:

- (a) stimulating a vagus nerve;
- (b) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (c) determining whether the measured characteristic of the heart is within a normal range for the patient; and
- (d) if the heart is operating outside the normal range, adjusting stimulation of the vagus nerve to bring the heart within the normal range.

Claim 79. (canceled)

The method of claim 78, wherein (d) includes adjusting at least one characteristic of stimulation pulses provided to the vagus nerve, wherein the characteristic is selected from the group consisting of pulse shape, inter-stimulus interval, pulse frequency, pulse width, pulse amplitude, and pulse phase.

Claim 80. (canceled)

The method of claim 78, wherein (d) includes the step of turning off stimulation to the vagus nerve.

Claim 81. (canceled)

The method of claim 78, further comprising:

- (e) operating a pacemaker to maintain the heart within the normal range.

Claim 82. (canceled)

The method of claim 78, further comprising:

- (e) alerting the patient by way of a sensory signal.

Claim 83. (canceled)

The method of claim 82, wherein (e) includes providing an audio signal to the patient.

Claim 84. (canceled)

The method of claim 82, wherein (e) includes providing a vibrating signal to the patient.

Claim 85. (canceled)

A method of minimizing effects to a heart of a patient comprising:

- (a) stimulating a vagus nerve;
- (b) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (c) determining whether the measured characteristic of the heart is within a predetermined range; and
- (d) if the heart is operating outside the predetermined range, alerting the patient by way of a sensory signal of effects to the heart caused by the vagus nerve stimulation.

Claim 86. (canceled)

The method of claim 85, wherein (d) includes providing an audio signal to the patient.

Claim 87. (canceled)

The method of claim 85, wherein (d) includes providing a vibrating signal to the patient.

Claim 88. (canceled)

The method of claim 85, further comprising:

- (e) operating a pacemaker to maintain the heart within the normal range.

Claim 89. (canceled)

The method of claim 85, further comprising:

- (e) turning off stimulation to the vagus nerve.

Claim 90. (original)

A method of minimizing effects to a heart of a patient comprising:

- (a) implanting at least one electrode to be communication with a vagus nerve of the body;
- (b) stimulating the vagus nerve with the at least one electrode;
- (c) identifying at least one phase of a heart pulse during which vagus nerve stimulation has reduced effect on the heart; and
- (d) providing stimulation only during the at least one identified phase of the heart pulse.

Claim 91. (original)

The method of claim 90, further comprising:

- (e) sensing an indication of a possible onset of a seizure.

Claim 92. (original)

The method of claim 91, wherein (e) includes sensing an electroencephalogram (EEG) of a patient.

Claim 93. (original)

The method of claim 91, wherein (e) includes sensing a cortical signal.

Claim 94. (original)

The method of claim 91, wherein (e) includes sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure.

Claim 95. (original)

The method of claim 91, wherein (e) includes sensing a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability

Claim 96. (original)

The method of claim 91, further comprising:

(f) if a possible seizure onset is detected, providing a warning of the possible seizure onset.

Claim 97. (original)

The method of claim 96, wherein (f) includes providing an audio signal.

Claim 98. (original)

The method of claim 96, wherein (f) includes providing a vibrating signal.

Claim 99. (original)

The method claim 90, further comprising:

- (e) determining whether the measured characteristic of the heart is within a predetermined range; and
- (f) if the heart is operating outside the predetermined range, alerting the patient by way of a sensory signal.

Claim 100. (original)

The method claim 90, further comprising:

- (e) determining whether the measured characteristic of the heart is within a predetermined range; and
- (f) if the heart is operating outside the predetermined range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

Claim 101. (original)

The method claim 90, further comprising:

- (e) determining whether the measured characteristic of the heart is within a predetermined range; and
- (f) if the heart is operating outside the predetermined range, turning off stimulation to the vagus nerve.

Claim 102. (new; claim 71 rewritten independently)

A system for treating epileptic seizures comprising in combination:

- (a) at least one electrode having a proximal end and a distal end adapted to provide stimulation to a vagus nerve of a patient;
- (b) a sensor for generating a sensor signal indicative of a characteristic of a heart;
- (c) an implantable signal generator coupled to the proximal end of the at least one electrode and providing stimulation energy in response to said sensor signal; and
- (d) a switch coupled to the signal generator and operable by the patient, whereby the patient may manually turn on or off the vagus nerve stimulation.

Claim 103. (new; claim 73 rewritten independently)

A system for treating epileptic seizures comprising in combination:

- (a) at least one electrode having a proximal end and a distal end adapted to provide stimulation to a vagus nerve of a patient;
- (b) a sensor for generating a sensor signal indicative of a characteristic of a heart;
- (c) an implantable signal generator coupled to the proximal end of the at least one electrode and providing stimulation energy in response to said sensor signal; and
- (d) a second sensor generating a second sensor signal indicative of a possible onset of a seizure, and wherein the signal generator is responsive to the second sensor signal, wherein the second sensor is implantable to be in communication with a brain of the patient.

Claim 104. (new; claims 75 and 76 combined and rewritten independently)

A system for treating epileptic seizures comprising in combination:

- (a) at least one electrode having a proximal end and a distal end adapted to provide stimulation to a vagus nerve of a patient;
- (b) a sensor for generating a sensor signal indicative of a characteristic of a heart wherein the signal generated by the sensor is of a heart pulse or a rate of change of a heart pulse; and
- (c) an implantable signal generator coupled to the proximal end of the at least one electrode and providing stimulation energy in response to said sensor signal.

Claim 105. (new; claim 80 rewritten independently)

A method of minimizing effects to a heart of a patient comprising:

- (a) stimulating a vagus nerve;
- (b) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (c) determining whether the measured characteristic of the heart is within a normal range for the patient; and
- (d) if the heart is operating outside the normal range, adjusting, including turning off, stimulation of the vagus nerve to bring the heart within the normal range.

Claim 106. (new; claim 89 rewritten independently)

A method of minimizing effects to a heart of a patient comprising:

- (a) stimulating a vagus nerve;
- (b) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (c) determining whether the measured characteristic of the heart is within a predetermined range;
- (d) if the heart is operating outside the predetermined range, alerting the patient by way of a sensory signal of effects to the heart caused by the vagus nerve stimulation; and
- (e) turning off stimulation to the vagus nerve.